MINUTES

KENTUCKY BOARD OF PHARMACY

Lexington, Kentucky

October 5, 2005

<u>CALL TO ORDER:</u> A regular meeting of the Kentucky Board of Pharmacy was held at the Board Office at Spindletop Administration Building, 2624 Research Park Dr., Lexington, Kentucky. President Edwards called the meeting to order at 9:16 a.m.

Members present: Mark Edwards, Becky Cooper, Georgina Jones, Greg Naseman, Peter Orzali, and Patricia Thornbury. Staff: Michael Burleson, Executive Director; Jeffrey L. Osman, Pharmacy Inspections and Investigations Coordinator; Steve Hart, Katie Busroe and Phil Losch, Pharmacy and Drug Inspectors; Lisa Atha, Executive Secretary; and Cheryl Lalonde, Assistant Attorney General and Board Counsel. Guests: Brian Fingerson, Pharmacist Recovery Network Committee; Ralph Bouvette and Allison Cubit, APSC; Paula York, Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services; John Hawks, Kentucky Pharmacists Association; Jan Gould, Kentucky Retail Federation; Chris Killmeier, Walgreens; Keith McFalls, Rx.com; Chris Stewart, Director of Pharmacy Services for Kentucky Medicaid; Bill Moore; Kevin West, attorney for Bill Moore; Jill Jones; Benjamin King and Jamey Wimsalt, University of Kentucky College of Pharmacy PY4 students; and Mike Leake and Catherine Shely, new Board appointees. Juanita Toole, Court Reporter, recorded the meeting.

MINUTES: On motion by Ms. Jones, seconded by Mr. Naseman and passed unanimously, the Minutes of September 14, 2005 were adopted as amended.

APPEARANCES: Jill Jones. Ms. Jill Jones had appeared before the Board on July 6, 2005 to petition for reinstatement of her Kentucky pharmacist's license. Ms. Jones again appeared before the Board on September 14, 2005. Ms. Jill Jones was placed under oath by Ms. Toole, Court Reporter. Mr. Naseman recognized Ms. Jill Jones's eagerness to comply with the requests of the Board from previous meetings. Ms. Jill Jones stated that she had been to Guesthouse and described that experience. She was again asking for reinstatement of her Kentucky pharmacist's license. Mr. Naseman moved to bring the original motion for reinstatement off the table. Ms. Thornbury seconded and the motion passed unanimously. Mr. Naseman moved to reinstate with an Order of Reinstatement with stipulations as follows: 10 years probation; maximum hours of work: 40 hrs/wk or 80 hrs/2wk, with exceptions to be approved by PRN Committee chairperson and notification provided to the Board; shall not serve as pharmacist-in-charge or have power of attorney during terms of probation; shall not be a preceptor; must provide copy of Agreed Order to all employers; must enter into an aftercare contract with PRN Committee, to include drug counselor if indicated; must submit signed release for Board

access to all medical records; must attend NA/AA meetings no less than 3 times per week; must submit to the Board written monthly reports of all NA/AA meetings; must submit to random observed urine/blood screens; shall be subject to quarterly inspections by the Board at all places of employment, with audits to be conducted if necessary, the cost of each inspection not to exceed \$500, may petition the Board to reduce the number of inspections five years from the date of the Agreed Order if all the conditions of the Agreed Order have been satisfied; perpetual inventory of Scheduled II, III, and IV drugs to be required at each place of employment; shall not ingest any mood altering substances whether legend or nonlegend medications including alcohol; notification to the Board within 10 days of all legend and nonlegend drugs prescribed/ingested; Board or Board President to approve all pharmacies/worksites prior to employment; shall not dispense any drugs for herself or her family members; shall obtain all prescriptions and those of family members at pharmacy designated in writing to the Board; attendance at the University of Utah School on Alcoholism and Other Drug Dependencies, the South Eastern PRN meeting, or the CAPTASA conference within one year; provide PRN Committee with a written self-performance evaluation monthly; shall make two appearances before the PRN Committee within one year; any violation of state and/or federal pharmacy or drug laws constitutes violation of Agreed Order and may result in an emergency suspension of pharmacist's license pursuant to KRS 315. The Agreed Order shall be reported to NABP. Order of Reinstatement to be drafted and forwarded to Ms. Jill Jones for her signature and upon its return to be signed by President Edwards. Mr. Orzali seconded, and the motion passed unanimously.

Billy Ray Moore: Billy Ray Moore and his attorney Mr. Kevin West were sworn in by Juanita Toole, Court Reporter. Mr. Moore appeared before the Board on June 8, 2005 to petition to be allowed to take the Kentucky Pharmacist Licensure Examination and if completed successfully, to have his Kentucky pharmacist's license reinstated. At that meeting the Board unanimously decided that more information from mental health professionals regarding Mr. Moore's treatment was needed. Mr. Moore and Mr. West were appearing before the Board to again request that Mr. Moore be allowed to take the Kentucky Pharmacist Licensure Examination and if completed successfully, to have his Kentucky pharmacist's license reinstated. Mr. Moore gave a brief update on his current treatment and events leading to disciplinary action by the Florida Board or Pharmacy. After some discussion, Mr. Naseman moved to deny the request to take the Kentucky Pharmacist Licensure Examination and thus denying the reinstatement of Mr. Moore's Kentucky pharmacist's license. Mr. Orzali seconded, and the motion passed unanimously.

Paul Sinclair: Mr. Sinclair was sworn in by Juanita Toole, Court Reporter. Mr. Sinclair appeared before the Board for clarification on the legality of the use of Medical Staff approved protocols that are procedure specific, not patient specific, in the hospital setting. After discussion, Ms. Thornbury moved for Mr. Burleson to send a letter to Mr. Sinclair with the clarification that 201 KAR 2:074, Section 4 (1) does allow for the use of these protocols as long as policies and procedures governing these functions have been developed by the pharmacist with input from others as needed and that an article appears in the Board Newsletter concerning this clarification. Mr. Orzali suggested that the

article thank Mr. Sinclair for bringing the issue before the Board and encourage others to appear before the Board with questions. Mr. Orzali seconded, and the motion passed unanimously.

Keith McFalls: Mr. McFalls was sworn in by Juanita Toole, Court Report. Mr. McFalls is the Vice President of Rx.com. He apologized that Mr. Carl Reeder was unable to attend the Board meeting. Mr. McFalls appeared before the Board to present the Rx.com business model and answer any questions regarding the model. Rx.Com operates under the central fill model. Rx.Com serves only as a fulfillment agent for the local pharmacy, leaving the prescription ownership, the prescription, the payment, and the relationship with the patient in the local pharmacy. The prescription data entry, the drug utilization review, the adjudication of claims, and the counseling of the patient are done at the local pharmacy. The filled prescription is returned to the local pharmacy or mailed to the patient as the patient directs. Rx.Com does charge a fee to the local pharmacy. After much discussion it was decided that 201 KAR 2:230 does not allow for the Rx.Com business model as presented in the Commonwealth of Kentucky. Mr. Naseman moved for Mr. Burleson to respond in writing to Rx.Com stating that there is a legal barrier per 201 KAR 2:230 but that the Kentucky Board of Pharmacy will review the regulation for possible amendment. Ms. Jones seconded and the motion passed unanimously.

BOARD REPORTS: President. 1. The Board Retreat is scheduled for November 12-13, 2005 at the Cincinnati Marriott in Covington, Kentucky. By consensus of the Board, agenda items will be technician registration, central fill/refill, Verified-Accredited Wholesale Distributors, and e-prescribing.

- **2.** The proposed regulatory changes to 201 KAR 2:020 were reviewed. After much discussion, Ms. Jones moved that Mr. Naseman, Mr. Burleson, Executive Director and Ms.LaLonde, Board Attorney review 201 KAR 2:020, making necessary changes and present a revised 201 KAR 2:020 at the December 14, 2005 Kentucky Board of Pharmacy meeting for consideration. Ms. Thornbury seconded and the motion passed unanimously.
- **3.** The proposed regulatory changes to 201 KAR 2:030 were reviewed. Mr. Orzali moved to accept 201 KAR 2:030 as presented. Mr. Naseman seconded and discussion ensued. After much discussion, Mr. Orzali moved to amend his original motion so as to accept 201 KAR 2:030 with amendment in Section 6 that the 750 hour requirement is stricken. Mr. Naseman seconded and more discussion ensued. After much discussion, Mr. Ozali removed the motion.
- **4.** The proposed regulatory changes to 201 KAR 2:050 were reviewed. Ms. Jones moved to remove Section 1 (2) from the regulation and to change Section 1 (9) to \$75. Mr. Naseman seconded and the motion passed unanimously. After much discussion this motion was withdrawn. Ms. Jones amended her original motion regarding 201 KAR 2:020 (see point 2. under Board Reports, President) to move that Mr. Naseman, Mr. Burleson, Executive Director and Ms. LaLonde, Board Attorney review 201 KAR 2:020, 201 KAR 2:030, 201 KAR 2:050, and any other regulations decided by this committee as

in need of review, make necessary changes and present the revised regulations at the December 14, 2005 Kentucky Board of Pharmacy meeting for consideration. Ms. Thornbury seconded and the motion passed unanimously.

Board Members: Ms. Thornbury stated that she would not be going to the National Community Pharmacists Association meeting in San Diego.

Board Executive Director:

1. Regulation 201 KAR 2:045 Section 1 (2) states that "a person be recognized by the board as a certified pharmacy technician if: (2) He has successfully completed the Nuclear Pharmacy Technician Training Program at the University of Tennessee." The Nuclear Pharmacy Technician Training Program at the University of Tennessee is no longer in existence. Ms. Thornbury moved to change the regulation to read, "a person be recognized by the board as a certified pharmacy technician if: (2) He has successfully completed a Nuclear Pharmacy Technician Training Program approved by the board." Mr. Naseman seconded and the motion passed unanimously.

PRN Chairperson: Brian Fingerson reported that he was presenting at the University of Kentucky College of Pharmacy, as well as the National Association of Drug Diversion Investigators – Kentucky Chapter and the South Eastern Pharmacist Recovery Network meetings.

CURRENT/PENDING CASES:

Ms. Lalonde, Board counsel, stated that a hearing date has been set for November 22, 2005 at 9 a.m. at the Board office, at Spindletop Administration Building, 2624 Research Park Dr., Lexington, Kentucky.

RECIPROCITY/RELICENSURE/INTERNSHIP:

Rajesh Hajari. Mr. Hajari requested that he be allowed to complete the last 100 hours of internship after the December 14, 2005 deadline for the January Kentucky Pharmacist Licensure Examination. He would complete his internship hours by Dec. 31, 2005. Ms. Thornbury moved to approve the request with proof of the completed 1500 internship hours to be submitted to the Board office by January 11, 2006. Ms. Cooper seconded and the motion passed motion.

CORRESPONDENCE/COMMUNICATIONS:

Scott Ross. Mr. Ross requested approval to be pharmacist-in-charge (PIC) of two permit holders, Save More Drugs and Save More LTC Pharmacy. Both permits would be located within the same physical location. Mr. Ross requested an exemption for reference material and equipment for Save More LTC Pharmacy. Because of the close proximity of the two permits, reference material and equipment would be shared. Ms.

Thornbury moved to approve Mr. Ross's request to serve as dual PIC and the shared use of reference material and equipment between the two permit holders. Ms. Jones seconded and the motion passed unanimously.

Terry Coyle. Mr. Coyle requested approval to be pharmacist-in-charge (PIC) of two permit holders, R & S Pulmonary Pharmacy in Campbellsville and R & S Pharmacy in Columbia. Ms. Thornbury moved to approve Mr. Coyle's request to serve as dual PIC. Ms. Cooper seconded and the motion passed unanimously. Mr. Naseman recused himself.

Netscript, WebMD. Mr. Bill Richardson requested a confirmation from the Kentucky Board of Pharmacy that the Netscript program meets the requirements of KRS 369 for electronic signatures. Mr. Naseman moved for Mr. Burleson to write a letter stating that the Net Script program did meet the requirements of KRS 369. Ms. Jones seconded and the motion passed unanimously.

Daniel Adams. Daniel Adams, pharmacist-in-charge of Rite Aid # 2290 requested permission for the pharmacists to sign a log after reviewing the daily printout instead of signing the daily printout. Mr. Naseman moved to deny the request. Mr. Orzali seconded and the motion passed unanimously.

Jeffrey L. Akers/Appalachian Regional Healthcare. Dr. Akers requested clarification regarding labeling of patient medication in a hospital setting. The specific question was when a nurse administers an IV piggyback medication obtained from an automated dispensing machine to a patient, and no mixing or compounding is required, does the nurse have to properly label the IV piggyback medication prior to administration. After discussion, Mr. Naseman moved to refer Dr. Akers to 201 KAR 2:074 Section 4 in its entirety and to refer him to the Kentucky Board of Nursing and Joint Commission on Accrediation for Healthcare Organizations for further clarification. Ms. Jones seconded and the motion passed unanimously.

<u>CONTINUING EDUCATION:</u> Ms. Jones moved to accept the continuing education programs 05-40 through 05-43 as recommended. Mr. Naseman seconded, and the motion passed unanimously.

OLD BUSINESS: Medicaid/Duragesic. Chris Stewart, Director of Pharmacy Services for Kentucky Medicaid, was sworn in by Juanita Toole, Court Report. Mr. Stewart appeared before the Board regarding generic substitution. He explained that Duragesic is 35% lower in cost to the state than generic fentanyl patches. He expects this to be a time limited event as more generics come onto the market and generics go down in price. Medicaid pharmacy outpatient regulation, allows for a preferred drug list. A Medicaid patient would pay the \$1 copay for Duragesic and the \$3 copay for generic fentanyl patches. After much discussion, Ms. Thornbury moved to respond to Mr. Ray DiPiero that since Duragesic is lower in price than generic fentanyl patches, KRS 217.822 dictates and allows dispensing of brand name, therefore, a pharmacist could and should dispense Duragesic in accordance with Medicaid policy. Mr. Burleson was directed to

publish this decision in the next Board Newsletter. Ms. Cooper seconded and the motion passed unanimously.

<u>NEW BUSINESS:</u> Examination. Ms. Cooper moved for acceptance of the final scores for the Kentucky Operative Examination and those candidates successful on the NAPLEX, Kentucky Operative Examination and the Kentucky Multistate Jurisprudence Examination be issued licenses. Ms. Jones seconded and the motion passed unanimously.

ADJOURNMENT: On motion by Ms. Jones, seconded by Ms. Cooper, and passed unanimously, President Edwards adjourned the meeting at 4:20 p.m. The next regularly scheduled Board meeting is scheduled to begin at 9:00 a.m. on December 14, 2005 at the Board Office at Spindletop Administration Building, Suite 302; 2624 Research Park Dr., Lexington, KY 40511.

Michael Burleson, Executive Director

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